



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/821,745

04/09/2004

Michael Snyder

1030.004

1863

25215 7590 04/01/2008  
DOBRUSIN & THENNISCH PC  
29 W LAWRENCE ST  
SUITE 210  
PONTIAC, MI 48342

EXAMINER

GHALI, ISIS A D

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

04/01/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/821,745	<b>Applicant(s)</b> SNYDER ET AL.	
	<b>Examiner</b> Isis A. Ghali	<b>Art Unit</b> 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/11/2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The receipt is acknowledged of applicants' election filed 01/15/2008; and IDS filed 03/11/2005.

Claims 1-10 and 12-20 have been canceled.

1. Applicant's election of invention III, claim 11, in the reply filed on 01/15/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 11 is pending and included in the prosecution.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 recites the limitation "the sustained release medium" in the 3<sup>rd</sup> line of the claim. There is insufficient antecedent basis for this limitation in the

Art Unit: 1611

claim. In the 4<sup>th</sup> line of the claim, applicants recite “a rate of flow”, and the examiner is wondering rate of flow of what. In the 7<sup>th</sup> line of the claim applicants recite “as matter is passed”, which matter? The same way applicants recite in the 7<sup>th</sup> line of the claim “changing dimension”, changing dimensions of what? Additionally, the claim is confusing as it recites contradicted limitations: “lumen for changing dimensions” and later in the 9<sup>th</sup> line of the claim applicants recite “fixed inner and outer dimension”.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,282,829 ('829) in view of US 5,278,202 ('202).

The present claim 11 is directed to implant with lumen and having openings in the wall and in its lumen comprises composition comprising caprolactone and antimicrobial agent. The lumen is circular and the sustained release material is solid.

US '829 teaches implant having interior hollow core filled with medicinal agent (abstract). The implant is porous to allow the controlled release of the medicinal agent in the core (col.5, lines 13-21). The medicinal agent includes antimicrobial agents in a vehicle that has no effect on integrity of the wall, if the wall is made of biodegradable materials such as caprolactone (col.6, lines 10-20). The implant has circular cross section (col.6, lines 66-68).

Although US '829 teaches inclusion of antimicrobial agent in vehicle that does not react with the wall of the implant if the wall is biodegradable, however, the reference does not explicitly teach the material of this vehicle.

US '202 teaches composition suitable for implantation comprising solid biodegradable polymer matrix including caprolactone including bioactive agent including antimicrobial agents that are released following the general rules of diffusion and dissolution of the polymer matrix (abstract; col.3, lines 15-30; col.4, lines 46-55; col.6, line 66).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide hollow implant having porous wall and antimicrobial agent in a vehicle in the core of the implant as disclosed by US '829, and replace the

vehicle of the antimicrobial agent with solid biodegradable caprolactone disclosed by US '202 because US '829 desired to have vehicle that does not degrade the biodegradable wall, and motivated by the teaching of US '202 that caprolactone is biodegradable and releases antimicrobial agents following the general rules of diffusion and dissolution of the polymer matrix, with reasonable expectation of having hollow implant having porous wall and antimicrobial agent in a caprolactone vehicle in the core of the implant that deliver the antimicrobial effectively from the biodegradable polymer.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Art Unit: 1611

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/  
Primary Examiner, Art Unit 1611

IG